Remarks

The Final Office Action mailed February 4, 2004 has been received and reviewed. Claims 1 and 16 having been amended, the pending claims are claims 1-3 and 12-20. Entry of the amendment submitted herewith is respectfully requested. Claims 16-20 having been withdrawn from consideration by the Examiner, as drawn to a non-elected invention, the claims under examination are 1-3 and 12-15. Reconsideration and withdrawal of the rejections are respectfully requested.

Support for amended claims 1 and 16 is found throughout the specification, for example, at page 9, lines 14-16 and page 12, lines 11-15 of the specification.

In the previous Response and Amendment, filed November 21, 2003, Applicants requested, pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86), the withdrawal of the Restriction Requirement, mailed October 4, 2001, and the rejoinder and examination of claims 16-20. Applicants note, with appreciation, the Examiner's acknowledgment of this request for rejoinder and his acknowledgment that the claims "will be considered when the product claims are found allowable."

Applicants also note, with appreciation, the Examiner's withdrawal of the rejection of claims 12 and 13 under 35 U.S.C. §103(a) as being unpatentable over Moore et al. (*General and Comparative Endocrinology, 98*:253-261 (1995)) in view of Hobart et al. (EU 46669 A1, March 3, 1982) and the Examiner's withdrawal of the objection of claim 3.

Examiner Interview

A telephonic Examiner Interview was held on February 27, 2004, with Examiner Ruixiang Li and Applicants' Representative Nancy Johnson. The rejection of the claims 1, 12, and 13 under 35 U.S.C. §112, first paragraph, and the rejection of claim 2 as anticipated by Moore et al. were discussed. Examiner Li is thanked for the courtesy of this interview.

Objection to the Specification

The Office Action Summary (page 1, item 9, Office Action mailed February 4, 2004) indicates that the specification is objected to by the Examiner. The Office Action contains no further discussion or explanation of this objection to the specification. It is believed that the box for item 9 was checked in error. Applicants in any event request withdrawal of this objection to the specification.

The 35 U.S.C. §102 Rejection

Applicants note, with appreciation, the Examiner's withdrawal of the rejection of claim 1 under 35 U.S.C. §102(b) as being anticipated by Moore et al. (*General and Comparative Endocrinology, 98*:253-261 (1995)).

The Examiner has however maintained the rejection of claim 2 under 35 U.S.C. §102(b) as being anticipated by Moore et al. (*General and Comparative Endocrinology, 98*:253-261 (1995)). Applicants respectfully traverse.

Specifically, the Examiner asserted that "[s]ince the somatostatin polypeptide . . . taught by Moore et al. comprises SEQ ID NO:2 . . . , the reference of Moore et al. meets the limitations of claim 2" (page 7 of Office Action mailed February 4, 2004). Applicants respectfully disagree.

Claim 2 is drawn to "[t]he somatostatin polypeptide of claim 1, wherein the somatostatin polypeptide comprises at least one amino acid sequence selected form the group consisting of SEQ ID NOs:2, 16, 17, 18, and 19." Applicants respectfully note that claim 2 is a dependent claim, depending from claim 1. Therefore, to properly anticipate claim 2, Moore et al. must disclose not only all of the elements recited in claim 2, but must also disclose all of the elements of independent claim 1, from which claim 2 depends.

Claim 1 as amended, is drawn to a somatostatin polypeptide comprising a polypeptide selected from the group consisting: of (a) a polypeptide comprising SEQ ID NO:15; (b) a subunit of the polypeptide of (a) comprising SEQ ID NO:16 and at least 7 contiguous amino acids from SEQ ID NO:17; and (c) an analog of the polypeptide of (a) that has an amino

acid sequence at least about 85% identical to SEQ ID NO:15, provided that the somatostatin polypeptide binds to a somatostatin receptor. Applicants respectfully submit, as the Examiner has previously acknowledged (pages 2-3, Office Action mailed August 21, 2003), Moore et al. teaches neither "(a) a polypeptide comprising SEQ ID NO:15," "(b) a subunit of the polypeptide of (a) comprising SEQ ID NO:16 and at least 7 contiguous amino acids from SEQ ID NO:17," nor "(c) an analog of the polypeptide of (a) that has an amino acid sequence at least about 85% identical to SEQ ID NO:15." Thus, Moore et al. does not disclose all the elements of claim 1, and therefore, Moore et al. cannot disclose all of the elements of dependant claim 2. Applicants respectfully submit that Moore et al. does not anticipate claim 2. Reconsideration and withdrawal of the rejection under 35 U.S.C. §102(b) is respectfully requested.

The 35 U.S.C. §112, First Paragraph, Enablement Rejection

The Examiner rejected claims 1, 12, and 13 under 35 U.S.C. §112, first paragraph, because the specification, while being enabling for polypeptides or fusion proteins comprising SEQ ID NOS: 2 and 15-19, does not reasonably provide enablement for an analog of SEQ ID NO:15 that has an amino acids sequence at least about 85% identical to SEQ ID NO:15 or a fusion protein comprising such an analog. Applicants respectfully traverse this rejection.

Claim 1 has been amended to recite a selected somatostatin polypeptide "*wherein the somatostatin polypeptide binds to a somatostatin receptor.*" Claims 12 and 13 are directed to fusion polypeptides comprising a somatostatin polypeptide as in claim 1.

The somatostatin polypeptides and fusion proteins of claims 1, 12, and 13 (as amended) are defined *structurally* in terms of amino acid sequence, i.e., "comprising a polypeptide selected from the group consisting of: (a) a polypeptide comprising SEQ ID NO:15; (b) a subunit of the polypeptide of (a) comprising SEQ ID NO:16 and at least 7 contiguous amino acids from SEQ ID NO:17; and (c) an analog of the polypeptide of (a) that has an amino acid sequence at least about 85% identical to SEQ ID NO:15." The specification provides comprehensive information for making and using somatostatin polypeptides and fusion proteins with the claimed amino acid sequences. See, for example, page 12, line 11 to page 13, line 8.

Further, claims 1, 12, and 13 have been amended to recite an additional distinguishing feature, i.e., "wherein the somatostatin polypeptide binds to a somatostatin receptor." The specification provides comprehensive information for making and using somatostatin polypeptides and fusion proteins with the binding activity recited in the claims. See, for example, page 9, lines 14-17, and Example V.

Applicants submit that the specification provides adequate instruction and guidance for somatostatin polypeptides and fusion proteins with the recited characteristics of claims 1, 12, and 13, as amended. Applicants respectfully request reconsideration and withdrawal of this rejection of the claims under 35 U.S.C. §112, first paragraph.

The 35 U.S.C. §112, First Paragraph, Written Description Rejection

The Examiner rejected claims 1, 12, and 13 under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Applicants respectfully traverse this rejection.

The Examiner asserted that the specification provides inadequate written description for part (c) of claim 1, somatostatin polypeptides comprising "(c) an analog of the polypeptide of (a) that has an amino acid sequence at least about 85% identical to SEQ ID NO:15." Specifically, the Examiner asserted that "the only factor present in the claim is a partial structure in the form of a recitation of percent identity," and thus claims 1, 12, and 13 "do not require that the polypeptide possess any particular biological activity, nor any particular conserved structure, or other disclosed distinguishing feature" (page 6, Office Action mailed February 4, 2004).

To meet the written description requirement of 35 U.S.C. §112, first paragraph, the application "must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, i.e., what is now claimed." M.P.E.P. § 2163. Factors to be considered in determining whether there is sufficient evidence of

possession include the level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention.

As noted above, claim 1 has been amended to recite a somatostatin polypeptide that binds to a somatostatin receptor, and claims 12 and 13 depend from claim 1. The claimed somatostatin polypeptides (claim 1) and fusion proteins (claims 12 and 13) are thus defined both in terms of amino acid sequence (percent identity) and in terms of binding activity. Amino acid sequence information and binding activity of the somatostatin polypeptide are taught in the specification (see, for example, page 12, line 11 to page 13, line 8, and, in addition, page 9, lines 14-17 and Example V).

Applicants further note that the level of knowledge and skill in the art is high. This is demonstrated by the information presented in Figure 5, demonstrating somatostatins from a wide range of vertebrates, including anglerfish (AF I), catfish (CF I), frog (FR I), chicken (C), rat (R), bovine (B), monkey (M), and human (H), have 39.1%, 44.9%, 50.0%, 49.5%, 48.0%, 49.8%, and 52.5% amino acid sequence identity to SEQ ID NO:15, respectively.

Applicants respectfully submit the present specification conveys with reasonable clarity to those skilled in the art that, as of the filing date, Applicants were in possession of the invention. Applicants respectfully maintain that they have satisfied the written description requirement for claims 1, 12, and 13. Accordingly, reconsideration and withdrawal of this rejection under 35 U.S.C. §112, first paragraph, is respectfully requested.

Summary

It is respectfully submitted that the pending claims 1-3 and 12-20 are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted for
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CERTIFICATE UNDER 37 CFR §1.8:

The undersigned hereby certifies that the Transmittal Letter and the paper(s), as described hereinabove, are being transmitted by facsimile in accordance with 37 CFR §1.6(d) to the Patent and Trademark Office, addressed to Assistant Commissioner for Patents, P.O. Box 1450, Mail Stop AF, Alexandria, VA 22313-1450, on this 24 day of **MARCH**, 2004, at 1:25 pm (Central Time).

By: _____
Name: SAM HER